PEARSON, J.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

JANE OLSZESKI, Plaintiff, v. ETHICON WOMEN'S HEALTH AND UROLOGY, *et al.*, Defendants.	)	CASE NO. 5:19CV1787 JUDGE BENITA Y. PEARSON **MEMORANDUM OF OPINION AND ORDER** [Resolving ECF No. 104]

Pending is Defendants Ethicon, Inc. and Johnson & Johnson's Amended Motion for Summary Judgment (ECF No. 104). The Court has been advised, having reviewed the record, the parties' briefs,[1] and the applicable law.[2] For the reasons set forth below, the motion is granted in part and denied in part.

I. Stipulated Facts

The stipulated facts[3] are as follows:

---

[1] Defendants' Fed. R. Civ. P. 56(c)(2) Objection (ECF No. 118 at PageID #: 9478-79) to the unsworn expert reports attached as exhibits to Plaintiff's Amended Response in Opposition to Defendants' Motion for Summary Judgment (ECF No. 117) is overruled. *See Davis v. United States*, 302 F. Supp.3d 951, 956 (S.D. Ohio 2017) (citing *Allen v. Shawney*, No. 11-10942, 2014 WL 1089618, at *9-10 (E.D. Mich. March 18, 2014), *aff'd*, No. 14-1510 (6th Cir. June 3, 2015)).

[2] During the *Daubert* hearing, the parties agreed that ECF No. 104 should be decided before the pending motions to strike report and/or exclude testimony of an expert witness (case-specific and general).

[3] *See* Joint Stipulation of Facts (ECF No. 101).

1. Plaintiff Jane Olszeski had two separate medical conditions, pelvic organ prolapse and stress urinary incontinence ("SUI"). Pelvic organ prolapse occurs when pelvic floor muscles weaken, allowing pelvic organs to drop (prolapse) into the vagina. Plaintiff had a third-degree cystocele (bladder prolapse), a third-degree rectocele (rectum prolapse) and a moderate uterine prolapse, meaning her pelvic organs were pressing against the opening to her vagina. *See* Corrected Deposition of Melissa Vassas, D.O. (ECF No. 104-2) at 48:4-11. SUI is the involuntary loss of urine with abdominal pressure, like sneezing, coughing or laughing. *Id.* at 22:5-22. Ms. Olszeski's prolapse was the primary reason for her surgery, but she also wanted her SUI fixed. *Id.* at 62:10-13.

2. Dr. Vassas performed surgery on February 24, 2009 in Canton, Ohio, and implanted an Ethicon TVT-O device to treat Plaintiff's SUI and a Boston Scientific Pinnacle device to treat her pelvic organ prolapse. Amended Complaint (ECF No. 56) at ¶¶ 5, 67.

3. Plaintiff is a resident of Ohio and has been at all times relevant to this matter. *Id.* ¶ 1. All of Ms. Olszeski's medical care and treatment related to her mesh devices occurred in Ohio. *Id.* ¶¶ 71-73; 78.

4. Dr. Vassas testified that she began using the TVT-O in 2005 or 2006, and she has considerable experience with mesh slings, placing approximately two to three mesh slings a week in her practice. ECF No. 104-2 at 22:23-23:7; *id.* at 24:17-24 ("Q. Is there any way for you to estimate how many patients you've treated surgically for stress urinary incontinence? A. Boy. You talk about two or three slings a week, and then, you know, minus vacations, times 18 years. Q. It sounds like it's a lot. A. Yeah. It's a lot.").

5. Before she performed Plaintiff's surgery, Dr. Vassas was aware of numerous potential risks and complications associated with the TVT-O, including the risks of chronic pain, scarring, chronic pain with intercourse (dyspareunia), bladder and bowel injury, nerve damage, inflammation, foreign body response, contraction of tissues, and recurrent incontinence. *Id.* at 123:1-5, 126:4-18, and Ex. 25. She also knew the risks of mesh curling or roping, an inability to remove the mesh, and neuralgia. *Id.* at 193:12-194:8.

6. Dr. Vassas did not rely on the TVT-O IFU in making her decision to use the TVTO or to learn the product's risks. *Id.* at 134:10-24 ("Q. At the time of the surgery in 2009, did you rely on the actual words in the IFU in your recommendation to plaintiff to have the TVT-O implanted? A. No. . . . Q. At the time of her surgery, did you rely on the actual words in the IFU to inform you about the risks related to plaintiff's TVT-O procedure? A. No, I did not rely on that."). She specifically testified that she does not "rely on the manufacturers to give me their information. I rely on my own experience and the literature." *Id.* at 226:4-9.

7. Dr. Vassas continues to believe that the TVT-O was an appropriate treatment for Ms. Olszeski, and she would not have changed her decision if additional warnings had been provided. *Id.* at 134:1-6 (noting additional warnings would not have changed her decision to use TVT-O to treat Plaintiff); at 135:12-17 ("Q. Putting yourself back at the time that you implanted Ms. Olszeski with the TVT-O but with the knowledge that you have today, do you agree that it was a reasonable and appropriate option for her? A. Yes."). Dr. Vassas also found the benefits of TVT-O outweighed the risks for Ms. Olszeski. *Id.* at 71:16-24.

8. Ms. Olszeski testified that she spoke with Dr. Vassas before having the TVT-O implanted and believed she was "a great doctor" and "wouldn't steer me wrong." Deposition of Jane Olszeski (ECF No. 104-3) at 131:7-19. In response to questioning as to whether she relied upon Dr. Vassas to select the best option for her, she responded "she was my doctor," and when asked whether she followed Dr. Vassas's recommendation, she testified, "Being I trusted her to take good care of me like she always does." *See id.*

9. While she was provided some product brochures, she cannot say what products those brochures related to or if any of them were about the TVT-O. *Id.* at 131:20-132:22.

10. Plaintiff disclosed Dr. Bruce Rosenzweig and Dr. Michael Hibner as case-specific medical expert witnesses concerning the cause of Ms. Olszeski's alleged injuries. *See* Plaintiff's Designation and Disclosure of Expert[ ] Witnesses (ECF No. 104-4).

11. Dr. Rosenzweig identifies alternative surgical procedures and non-mesh products as proposed safer alternatives to the TVT-O, including "the Burch procedure with delayed absorbable sutures like PDS" and an "autologous fascia sling." Case Specific Expert Report of Bruce Rosenzweig, M.D. (ECF No. 104-5) at 28. He testified that these surgical procedures would not have eliminated the risk of pelvic pain and dyspareunia. Deposition of Bruce A. Rosenzweig, M.D. (ECF No. 104-6) at 166:3-8.

12. Dr. Rosenzweig also identifies an "allograft sling such as Repliform" and a "sling with less polypropylene such as Ultrapro" as possible alternatives because they "reduce[ ] the risk of injury to the soft tissues . . . and reduce the risk of injury to the obturator or pudendal nerve." ECF No. 104-5 at 28. He also indicates in his Report that an allograft and Ultrapro sling

"reduce the risk of acute injury or irritation to adjacent nerves at the time of implant and reduce secondary nerve entrapment" and there is "less degradation, mesh shrinkage and scarification." *Id.* As to Repliform, Dr. Rosenzweig agrees that, if it had been placed via a transobturator route, there was still the risk of "pudendal neuralgia, obturator neuralgia, dyspareunia, and pelvic pain." ECF No. 104-6 at 161:11-18.

13. As to Ultrapro, Dr. Rosenzweig agrees that "Ultrapro has never been marketed, sold, or used . . . by doctors to treat women in the United States for stress urinary incontinence." *Id.* at 156:4-9. He testified that in 2009, when Mrs. Olszeski had her surgery, the implanting surgeon could have used Ultrapro "off label" to treat stress urinary incontinence. *Id.* at 156:10-14. He further agreed that a product made of Ultrapro would still carry the "risk of pudendal or obturator neuralgia" if placed as designed for the TOPA product using Ultrapro that never came to market and it also had the risk of pudendal neuralgia if place retropubically. *Id.* at 156:17-157:2. Dr. Rosenzweig also agrees that a sling with Ultrapro would not have eliminated the risks of "pelvic pain or dyspareunia." *Id.* at 157:3-5. He also testified that a component of Ultrapro (absorbable monocryl) "can lead to a more – greater inflammatory response, but not greater scarring." *Id.* at 157:8-13. An Ultrapro sling also has a risk of "mesh exposures," "degradation or deformation or cytotoxicity." *Id.* at 159:11-20.

14. Dr. Rosenzweig opined that a "retropubic sling (while defective) reduces the risk of obturator nerve injury" and "reduces the risk of pudendal nerve injury." ECF No. 104-5 at 28. He testified that a retropubic sling "just decreases the risk" of obturator nerve injury, but it is also a product that is defective in design. ECF No. 104-6 at 152:12-20 ("Q. Do you believe that the

Ethicon TVT retropubic sling is defective in design? A. I said that in my report. Q. I would like to hear it right now so I could ask you some questions about it. A. Yes. Q. So you believe it's defective but it's safer than the TVT-O? A.Yes. For Ms. Olszeski."). He testified that "a TVT retropubic sling cannot prevent or remove or eliminate the risk of pudendal neuralgia," *id.* at 153:21-24, "cannot eliminate the risk of dyspareunia," *id.* at 154:8-10, "cannot eliminate the risk of pelvic pain," *id.* at 154:11-13, and cannot eliminate the risk of "sexual dysfunction," *id.* at 154:14-16.

15. In his report, Dr. Hibner identifies a retropubic sling as a safer alternative to TVTO. Rule 26 Expert Report of Michael Hibner, MD, PH. D (ECF No. 104-8) at 15. Dr. Hibner testified that, while a retropubic sling is safer than a TVT-O, "in no way am I saying it's safe." Deposition of Michael Hibner, M.D. (ECF No. 104-7) at 76:11-14. He also testified that a retropubic sling "lowers . . . but I don't think it eliminates" the risk of pudendal neuralgia, pelvic pain and dyspareunia. *Id.* at 76:15-77:3. He cannot say any synthetic sling available in 2009 would eliminate the risks of pudendal neuralgia, pelvic pain, or other nerve damage to Ms. Olszeski. *Id.* at 77:4-18 ("Q. Doctor, are you aware of any synthetic sling that was on the market in 2009 that would have prevented or eliminated the risk of pudendal neuralgia in Ms. Olszeski? A. Completely eliminated? No. Q. Same question for pelvic pain or dyspareunia? A. Same answer. Q. Same question for any other nerve damage. A. Same answer." (counsel objections omitted)).

16. At his deposition, Dr. Hibner identified allograft slings like Repliform as an alternative to the TVT-O, but he testified that an allograft sling still has a risk of pudendal and

obturator neuralgia, pelvic pain and dyspareunia. *Id.* at 77:20-78:8. He testified that Ultrapro mesh is "only used in Europe" to treat stress urinary incontinence and was not available for doctors to use in the treatment of SUI in 2009. *Id.* at 78:14-24. He also testified that Ultrapro still had the risk of pudendal and obturator neuralgia, pelvic pain, and dyspareunia. *Id.* at 78:25-79:7. He also admitted that a Burch procedure using no mesh has the risk of pudendal and obturator neuralgia, pelvic pain, and dyspareunia. *Id.* at 79:22-80:8.

17. Dr. Hibner testified that he cannot say that Ms. Olszeski's TVT-O degraded, shrunk, had an excessive foreign body response, had an excessive inflammatory response, or caused excessive scarring, and he also cannot say that any of these alleged conditions is causing her complaints of injury. *Id.* at 83:10-85:14 ("Q. Doctor, in terms of the degradation or shrinkage of the mesh, are you aware of any objective medical evidence in Ms. Olszeski's records that document those phenomenon? A. No. Q. Are you aware of any objective medical evidence in Ms. Olszeski's medical records that either of her meshes underwent deformation, fraying roping, cording or curling? A. No, I'm not. Q. Are you aware of any objective medical evidence in Ms. Olszeski's records that her TVT-O was too rigid and caused problems? A. I am not. Q. Are you aware of any objective medical evidence in Ms. Olszeski's medical records that the TVT-O was too sharp or lost pore size? A. I'm not. Q. Doctor, are you aware – strike that. Doctor, can you point to any objective medical evidence in Ms. Olszeski's records that degradation or shrinkage of the mesh contributed or caused any of her complaints in this case? A. No, I can't. Q. Are you aware of any objective medical evidence in Ms. Olszeski's records that demonstrate that deformation or fraying, roping, cording or curling of any of her meshes contributed to any of her

complaints in this case? A. No, I cannot. Q. Same question regarding the rigidity of the mesh or the sharpness of the mesh? A. I cannot. Q. Same question regarding the loss of pore size of the mesh? A. No, I cannot. Q. Are you aware of any objective medical evidence in Ms. Olszeski's records that supports a conclusion that there was an excessive foreign body reaction that took place with either of her meshes? A. No, I cannot. I know there was evidence that there was scarring, so that's a reaction to the foreign body. Q. But scarring is an anticipated result any time you perform a surgical incision, correct? A. That's true, but you know, how do you medically define an excessive foreign body reaction. Like where do you draw the line between normal and excessive. Q. Are you able to draw that line quantitatively in Ms. Olszeski's case? A. No, I don't think anyone can.").

18. Ms. Olszeski originally filed a complaint against Boston Scientific in 2013 in the Boston Scientific MDL pending in the Southern District of West Virginia and alleged claims against Ethicon in that case, which were subsequently dismissed without prejudice in the MDL Court. In August 2019, Ms. Olszeski filed the pending lawsuit against Ethicon in the Northern District of Ohio. When her case against Boston Scientific was remanded from the MDL to the Northern District of Ohio, the cases were consolidated for trial. In her Amended Complaint (ECF No. 56), Plaintiff asserts four claims under the Ohio Product Liability Act ("OPLA"): manufacturing defect (Count I), design defect (Count II), failure to warn (Count III), and non-conformance with representation (Count IV).

II. Background

Plaintiff's implanting physician is Melissa S. Vassas, D.O. On February 24, 2009, Plaintiff underwent a procedure that included IUD removal, hysteroscopy, and the implantation of two mesh devices, the Ethicon TVT-O polypropylene sling and the Boston Scientific Corp. Pinnacle polypropylene device, in her lower pelvis. Ethicon's Gynecare TVT-Obturator pelvic mesh product treated Plaintiff's SUI, and was installed through her left obturator muscle. Boston Scientific's Pinnacle Pelvic Floor Repair Kit treated Plaintiff's pelvic prolapse, and was installed through her sacrospinous ligament. Plaintiff first filed a Complaint in 2013. In Plaintiff's Amended Complaint (ECF No. 56), Plaintiff is pursuing both defective design and failure to warn claims under Ohio law regarding these polypropylene pelvic mesh products. Plaintiff also maintains a non-conformance with representation claim against Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon" or "Defendants"). Whether Plaintiff's claimed injuries were caused by her Gynecare TVT-Obturator (the "TVT-O") (a sling manufactured by Ethicon) or her Pinnacle Pelvic Floor Repair Kit (the "Pinnacle") (manufactured by Boston Scientific) is a primary issue in this case. Plaintiff's "primary disabling conditions are right and left pudendal neuralgia and right and left obturator neuralgia," (2) that her "[r]ight and left pudendal neuralgia . . . is the primary cause of her dyspareunia," "bladder symptoms," "pelvic pain" and "lack of clitoral sensation," and that her mesh implants are also responsible for "Erosion, pelvic floor dysfunction, [and] levator spasm." ECF No. 104-8 at PageID #: 4894-4900. Plaintiff had mesh removal surgeries on October 21, 2019, July 9, 2020, and July 13, 2021.

Plaintiff's design defect claim (Count II; Ohio Rev. Code § 2307.75), failure to warn claim (Count III; Ohio Rev. Code § 2307.76), nonconformance with representation claim (Count IV; Ohio Rev. Code § 2307.77), and punitive damages claim (Count V), in the Amended Complaint (ECF No. 56) remain pending.[4]

III. Standard of Review

Summary judgment is appropriately granted when the pleadings, the discovery and disclosure materials on file, and any affidavits show "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Johnson v. Karnes*, 398 F.3d 868, 873 (6th Cir. 2005). Fed. R. Civ. P. 56(c)(1)(a) requires a party requesting summary judgment in its favor or an opposing party "to go beyond the pleadings" and argument, *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986), and cite to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." The moving party must "show that the non-moving party has failed to establish an essential element of his case upon which he would bear the ultimate burden of proof at trial." *Guarino v. Brookfield Twp. Trustees.*, 980 F.2d 399, 403 (6th Cir. 1992).

Once the movant makes a properly supported motion, the burden shifts to the non-moving party to demonstrate the existence of genuine dispute. An opposing party may not simply rely on

[4] In August 2021, the Court approved Plaintiff and Defendants Ethicon, Inc. and Johnson & Johnson's Joint Proposed Stipulation of Partial Dismissal as to Manufacturing Defect Claim (Count I) With Prejudice. *See* ECF No. 96.

its pleadings. Rather, it must "produce evidence that results in a conflict of material fact to be resolved by a jury." *Cox v. Ky. Dep't. of Transp.*, 53 F.3d 146, 150 (6th Cir. 1995). The non-moving party must, to defeat the motion, "show that there is doubt as to the material facts and that the record, taken as a whole, does not lead to a judgment for the movant." *Guarino*, 980 F.2d at 403. In reviewing a motion for summary judgment, the court must view the evidence in the light most favorable to the non-moving party when deciding whether a genuine issue of material fact exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970).

The United States Supreme Court, in deciding *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), stated that in order for a motion for summary judgment to be granted, there must be no genuine issue of material fact. *Id.* at 248. The existence of some mere factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. *Scott v. Harris*, 550 U.S. 372, 380 (2007). A fact is "material" only if its resolution will affect the outcome of the lawsuit. In determining whether a factual issue is "genuine," the court must decide whether the evidence is such that reasonable jurors could find that the non-moving party is entitled to a verdict. *Id.* Summary judgment "will not lie . . . if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* To withstand summary judgment, the non-movant must show sufficient evidence to create a genuine issue of material fact. *Klepper v. First Am. Bank*, 916 F.2d 337, 342 (6th Cir. 1990). The existence of a mere scintilla of evidence in support of the non-moving party's position ordinarily will not be sufficient to defeat a motion for summary judgment. *Id.* (citing *Anderson*, 477 U.S. at 252).

IV. Analysis

A. Design Defect Claim (Count II; Ohio Rev. Code § 2307.75)

1. Alternative Product Design

Defendants argue Plaintiff's design defect claim should be dismissed because she has no proof of a safer alternative design that would have prevented her injuries or the required proof of the product defect that caused injury.

Under Ohio Rev. Code § 2307.75(F), a product is not defective in design or formulation if a "technically feasible alternative design or formulation was not available" at the time the product was manufactured. *See Burris v. Ethicon, Inc.*, No. 3:20CV1450, 2021 WL 3190747, at *5 (N.D. Ohio July 28, 2021) (noting requirement to establish "a practical and technically feasible alternative design" to the product at issue); *McGrath v. Gen. Motors Corp.*, 26 Fed.Appx. 506, 510 (6th Cir. 2002) (design defect claim requires a plaintiff to prove that risks exceed benefits and feasible alternative design would have prevented harm without reducing product's usefulness or purpose) (Ohio law). In addition, the OPLA requires that plaintiff establish that the proposed alternative design "would have prevented" the harm alleged. *See* Ohio Rev. Code § 2307.75(F); *Zang v. Cones*, 34 N.E.3d 955, 961 (Ohio App. 1st Dist. 2015) (Ohio law requires plaintiffs to establish that a proposed alternative feasible design "would have prevented the harm for which the plaintiff seeks to recover" with expert testimony). If a plaintiff fails to establish either element with expert evidence, Ohio courts recognize that summary judgment is warranted. *See Yanovich v. Sulzer Orthopedics, Inc.*, No. 1:05CV2691, 2006 WL 3716812, at *13 (N.D. Ohio Dec. 14, 2006) (granting summary judgment on plaintiff's design

defect claim related to a medical device because plaintiff's expert offered no evidence of a design available on the marketplace at the time of the surgery that would have prevented the injury), *aff'd*, 255 Fed.Appx. 957 (6th Cir. 2007); *see also Hutchens v. Abbott Labs., Inc.*, 2016 WL 5661582, at *4 (N.D. Ohio Sept. 30, 2016) (summary judgment proper on design defect due to "the absence of expert testimony that a feasible alternative design would have *prevented* the harm") (emphasis added).

Plaintiff's case specific expert, Dr. Rosenzweig, offers the following alternatives: a Burch procedure using sutures, an autologous fascia sling (made from tissue harvested from the patient), an allograft sling called Repliform (made of cadaver tissue), a sling made of Ultrapro mesh (hernia mesh), and a retropubic sling, like Ethicon's TVT midurethral sling. ECF No. 104-5 at 28-29; ECF No. 101 at ¶¶ 11-15. While he opines that certain of these alternatives would have reduced the risk of obturator neuralgia, he could not say at deposition that any of these alternatives would have prevented injury to Plaintiff. According to Defendants, all of these alternatives to the TVT-O have been rejected by courts as alternatives for synthetic mesh products and/or would not have prevented Plaintiff's injuries.

Another case specific expert for Plaintiff, Dr. Hibner, offers only one claimed product alternative in his report: a retropubic sling, like TVT. ECF No. 104-8 at 15; *see also* ECF No. 104-7 at 74:17-75:10; ECF No. 101 at ¶ 15. At his deposition, he also discussed biologic mesh and Ultrapro as alternatives. *See* ECF No. 104-7 at 78:09-79:04. Defendants argue that assuming, *arguendo*, that these untimely opinions were allowed, they do not suffice to meet

Plaintiff's burden. Dr. Hibner expressed his views on Ultrapro and biologic allograft slings in his deposition through questions proffered by defense counsel.

2. Whether There is Sufficient Causation Proof to Sustain a Design Defect Claim

Defendants second and independent basis for dismissal of Count II is that Plaintiff lacks expert proof as to what TVT-O defect caused her injuries. Ohio Rev. Code. § 2307.73(A)(2) (subjecting manufacturers to liability only if, among other things, "[a] defective aspect of the manufacturer's product in question as described in division (A)(1) [including "defective in design"] of this section was a proximate cause of harm for which the claimant seeks to recover compensatory damages"); *Tsirikos-Karapanos v. Ford Motor Co.*, 99 N.E.3d 1203, 1209 n.2 (Ohio App. 8th Dist. 2017) (for a design defect claim, a plaintiff must show "the defect was the direct and proximate cause of the plaintiff's injuries or loss"); *Utz v. Howmedica Osteonics Corp.*, No. 1:06 CV 1963, 2009 WL 5409046, at *10 (N.D. Ohio March 31, 2009) (granting summary judgment to defendants when "Plaintiffs lack direct evidence that a defect in the design of the [spinal rod system] caused Utz's injury"); *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 529 (6th Cir. 2012) (applying Ohio law) ("Ohio law requires expert testimony where aspects of the defect or the proposed alternative designs are technically complex and outside the understanding of a lay juror.").

In response, Plaintiff offers expert proof that the TVT-O causes chronic pelvic pain syndromes, chronic dyspareunia and sexual impairment, nerve injuries, de novo urinary symptoms, vaginal scarring/banding, mesh erosion, pelvic organ dysfunction, the need for multiple revision surgeries that may not address the problems, and other complications, including

death. *See* Rule 26 Expert Report of Jerry G. Blaivas, M.D. (ECF No. 117-2) at 4-5, 11, 19. Additional complications include chronic groin pain, chronic thigh pain, obturator nerve injury/neuralgia, and pudendal nerve injury/neuralgia. *See* ECF No. 104-5 at pp. 3-11; Rule 26 Expert Report of Bruce Rosenzweig, M.D. (ECF No. 117-4) at 48-57; ECF No. 104-8 at 12-19. Dr. Hibner testified in his deposition that the TVT-O caused or contributed (along with the Pinnacle device) to the pudendal and obturator neuralgia injuries sustained by Plaintiff. *See* ECF No. 104-7 at 128:12-21. Dr. Hibner went on, in his deposition, to describe that the TVT-O likely caused or contributed to all of the symptoms Plaintiff suffered. *See* ECF No. 104-7 at 128-33. Under Ohio law, this testimony, as well as both expert's reports, provide more than sufficient evidence of causation.

B. Failure to Warn Claim (Count III; Ohio Rev. Code § 2307.76)

According to Defendants, Plaintiff's failure to warn claim fails because of three separate and independent grounds: (1) the implanter, Dr. Melissa Vassas, did not rely on the TVT-O product warnings; (2) she already knew the risks of complications that Plaintiff claims here; and, (3) additional warnings would not have changed her decision to recommend and use the TVT-O.

"To prevail on a failure to warn claim under Ohio law, a plaintiff must prove three elements: (1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) *an injury proximately caused by the breach*." *Burris*, 2021 WL 3190747, at *5 (emphasis added) (citing *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003)); Ohio Rev. Code § 2307.76(A)(1). Ohio law provides that "[a] plaintiff not only must convince the fact finder that the warning provided is unreasonable, hence inadequate, but he also must establish the existence

of proximate cause between the [product] and the fact of the plaintiff's injury." *Miller v. ALZA Corp.*, 759 F. Supp.2d 929, 936 (S.D. Ohio 2010) (quoting *Hisrich v. Volvo Cars of N. Am., Inc.*, 226 F.3d 445, 450-51 (6th Cir. 2000)). As the Court has previously recognized, a "[p]roximate causation analysis concerns two separate issues: (1) whether lack of adequate warnings contributed to the plaintiffs' [use] of the [product], and (2) whether [use] of the [product] constitutes a proximate cause of the plaintiff's injury." *Heide v. Ethicon, Inc.*, No. 4:20CV0160, 2020 WL 1322835, at *5 (N.D. Ohio March 20, 2020) (Pearson, J.) (brackets in original) (citing *Sheffer v. Novartis Pharms. Corp.*, No. 3:12CV0238, 2013 WL 5276558, at *11 (S.D. Ohio Sept. 18, 2013)). Plaintiff must show that her physician would have acted differently had she been given an adequate warning. *Id.* (citing *Contreras v. Bos. Sci. Corp.*, No. 2:12-cv-03745, 2016 WL 1436682, at *4 (S.D.W. Va. April 11, 2016); *Fulgenzi v. PLIVA*, 140 F. Supp.3d 637, 648 (N.D. Ohio 2015); *Higgins v. Ethicon, Inc.*, No. 2:12-cv-01365, 2017 WL 2813144, at *3 (S.D.W. Va. Mar. 30, 2017)).

Under Ohio law, "where no warning is given, or where an inadequate warning is given, a rebuttable presumption arises, beneficial to the plaintiff, that the failure to adequately warn was a proximate cause of the plaintiff's [use] of the [product]. This presumption, absent the production of rebutting evidence by the defendant, is sufficient to satisfy the first branch of the plaintiff's proximate cause burden." *Seley v. G.D. Searle Co.*, 67 Ohio St.2d 192, 200 (1981) (citations omitted). According to Plaintiff, the rebuttable presumption exists under the facts of the case at bar because Defendants have not disputed that the warnings on its TVT-O IFU were inadequate. *See* ECF No. 117 at PageID #: 8349. Whether Plaintiff has satisfied the "first branch" of

proximate causation – whether the inadequate warning played a role in the use of the device – is a matter for the jury to decide.

1. Dr. Vassas' Reliance on the Product Warnings

Dr. Vassas did not rely on the TVT-O Instructions for Use ("IFU") in making her decision to use the TVT-O or to learn the product's risks. Joint Stipulation of Facts (ECF No. 101) at ¶ 6. Defendants argue that the implanter also did not rely on Ethicon or the product warnings in making her decision to use the TVT-O in Plaintiff's treatment. *See* ECF No. 104 at PageID #: 3846 (citing ECF No. 101 at ¶ 6). If Plaintiff cannot establish causation on her failure to warn claim, the Court should dismiss it. *See Hosbrook v. Ethicon, Inc.*, No. 3:20-cv-88, 2021 WL 1599199, at *9 (S.D. Ohio April 23, 2021) (in a case applying Tennessee law, plaintiff could not show that implanter relied on warnings, and thus could not establish causation on failure to warn claim); *Cutter v. Ethicon, Inc.*, No. 5:19-443-DCR, 2020 WL 109809, at *8 (E.D. Ky. Jan. 9, 2020) (granting summary judgment on failure to warn claim when physician did not rely on warnings).

Plaintiff argues she can establish causation on her failure to warn claim. Contrary to Defendants' contention, Dr. Vassas testified that prior to using a product for the first time, including mesh, she takes it upon herself to familiarize herself with the product information and particularly the safety information. When Dr. Vassas first encountered the TVT-O during her residency, she did read the IFU as part of her training to learn how to implant it. *See* ECF No. 104-2 at 131:12-19. Dr. Vassas also testified that at the time of Plaintiff's surgery in 2009, she believed the IFU to be complete, truthful, and accurate. *See* ECF No. 104-2 at 190:5-8.

Additionally, Dr. Vassas testified that when deciding whether to implant a patient with mesh, that the more relevant information she has, the better her decision is going to be, and agreed that if she was missing relevant information, it would become more difficult to adequately treat a patient. *See* ECF No. 104-2 at 192:15-23. Finally, Dr. Vassas agreed it is the manufacturer's responsibility to ensure a marketed product is safe for surgical implantation, efficacious, and a device manufacturer like Ethicon should test and produce reliable data about the device before marketing it. *See* ECF No. 104-2 at 228:23-229:5; 229:6-11. She further said she believed Ethicon would have performed clinical trials of the TVT-O before putting it on the market, and if it had not done that, it would have affected her decision to use it. *See* ECF No. 104-2 at 229:12-19. Such evidence is sufficient to raise a genuine issue of material fact. While Dr. Vassas did not necessarily read the IFU immediately prior to every implantation of a TVT-O she performed, she had read the IFU prior to implantation, unlike the user of the product in *Fulgenzi*, *supra*.

2. Whether Dr. Vassas Knew About the Risks of Complications That Plaintiff Alleges

Defendants argue that Plaintiff cannot establish causation because, "[b]efore she performed Plaintiff's surgery, Dr. Vassas was aware of numerous potential risks and complications associated with the TVT-O, including the risks of chronic pain, scarring, chronic pain with intercourse (dyspareunia), bladder and bowel injury, nerve damage, inflammation, foreign body response, contraction of tissues, and recurrent incontinence. She also knew the risks of mesh curling or roping, an inability to remove the mesh, and neuralgia." Joint Stipulation of Facts (ECF No. 101) at ¶ 4 (citations omitted). *See Cutter*, 2020 WL 109809, at

*8 (plaintiff cannot show proximate cause on failure to warn claims because implanter knew risks); *Sharp v. Ethicon, Inc.*, No. 2:20-CV-2028, 2020 WL 1434566, at *4 (W.D. Ark. March 24, 2020) (failure to warn claim dismissed when, *inter alia*, physician knew risks); *Nix v. Ethicon, Inc.*, No. 1:19-cv-04896-SCJ, 2020 WL 5525172, at *2 (N.D. Ga. Sept. 14, 2020) (same).

Plaintiff retorts, while Dr. Vassas was aware of some of the risks of the Ethicon TVT-O, she did not know of all risks and complications of the TVT-O device. Based on her testimony regarding pudendal neuralgia, she was not independently "aware" of these risks such to eliminate Ethicon's duty to warn. *See* ECF No. 104-2 at 167:15-18 ("I'm not an expert in neuralgias."); 172:17-23; and 175:2-5 ("I've never seen [pudential neualgia pain syndrome]").

3. Whether Dr. Vassas Would Have Changed Her Treatment Decision

Defendants contend that even if additional or different warnings were given, Dr. Vassas would not have changed her prescribing decision. *See* Joint Stipulation of Facts (ECF No. 101) at ¶ 7. According to Defendants, this is yet another fatal causation hurdle that Plaintiff cannot overcome.

Whether Dr. Vassas would have changed her treatment decision is speculative and best resolved by a jury. Defendant cites to deposition testimony by Dr. Vassas to support its argument. The testimony reads: "Q. Putting yourself back at the time you implanted Ms. Olszeski with the TVT-O[,] but with the knowledge that you have today, do you agree that it was a reasonable and appropriate option for her? A. Yes." ECF No. 104-2 at 140:12-16. Dr. Vassas testified, however, that she is "not an expert in neuralgias," had "never seen" a case of pudendal

neuralgia, did not know whether pudendal neuralgia was a life-altering pain syndrome, and did not think polypropylene mesh causes catastrophic changes long-term. *See* ECF No. 104-2 at 167:15-18; 172:17-23 ("I don't think it causes catastrophic changes long-term."); and 175:2-5. This testimony stands in contrast to that of the physician in *Miller*, *supra*, cited by Defendants. In that case, "with regard to the risk of leaking patches, Dr. Hale [the prescribing physician] testified unequivocally that he would have prescribed the patch even if specifically warned that 'it is impossible to produce patches 100 percent no fentanyl gel leaks[.]' " 759 F. Supp.2d at 936-37 (brackets in original). With no such testimony in the case at bar, summary judgment on Plaintiff's failure to warn claim (Count III) would be improper.

C. Non-conformance With Representation Claim (Count IV; Ohio Rev. Code § 2307.77)

Defendants contend Plaintiff's nonconformance with representation claim should be dismissed because neither Plaintiff nor Dr. Vassas relied on information from Ethicon or Johnson & Johnson in deciding to use the TVT-O in Plaintiff's treatment.

Under the OPLA, "[a] product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer." Ohio Rev. Code § 2307.77. " 'Representation' means an express representation of a material fact concerning the character, quality, or safety of a product." Ohio Rev. Code § 2307.71(A)(14).

To recover on Count IV, Plaintiff must show "(1) that the manufacturer made a representation as to a material fact concerning the character or quality of the manufacturer's product; (2) that the product did not conform to that representation; (3) that the plaintiff justifiably relied on that representation; and (4) that the plaintiff's reliance on the representation

was the direct and proximate cause of the plaintiff's injuries." *Tomlin v. Smith & Nephew, Inc.*, No. 3:19-cv-354, 2020 WL 5230830, at *2-3 (S.D. Ohio Sep. 2, 2020) (citing *Gawloski v. Miller Brewing Co.*, 96 Ohio App.3d 160, 165 (Ohio App. 9th Dist. 1994)); *see also* *Krumpelbeck v. Breg. Inc.*, 491 Fed.Appx. 713, 721-22 (6th Cir. 2012) (Ohio law); *Saraney v. TAP Pharm. Prods., Inc.*, No. 1:04CV2026, 2007 WL 148845, at *5, 8 (N.D. Ohio Jan. 16, 2007).

According to Plaintiff, her claim for non-conformance with representations succeeds for the same reasons her failure to warn claim succeeds. Dr. Vassas testified that at the time of Plaintiff's implantation surgery in 2009, she believed that Ethicon had put complete and truthful and accurate information in the TVT-O IFU. *See* ECF No. 104-2 at 190:5-8. The TVT-O IFU contains material representations by Ethicon regarding the safety, risks, and complications associated with that product. Dr. Vassas acknowledged the IFU was intended for her benefit as a surgeon, and, in fact, trusted the veracity of the IFU enough to provide that document to her patients. The evidence Plaintiff relies on in the record demonstrates that whether the TVT-O IFU was deficient and failed to conform to the representations regarding the risks and complications of that product is a jury question.

D. Punitive Damages (Count V)

Plaintiff generally asserts a "claim" for punitive damages, *see* ECF No. 56 at PageID #: 836-39. It is not, however, a separate claim for relief. Rather, it is a potential element of recovery. *Beair v. Ohio Dept. of Rehabilitation*, 156 F. Supp.3d 898, 907 (N.D. Ohio 2016) (dismissing claim for punitive damages "because there is no such freestanding cause of action under Ohio or federal law"). Defendants correctly argue that should the Court grant summary

judgment on Plaintiff's claims under the Ohio Product Liability Act, this lawsuit would be dismissed with prejudice in its entirety because punitive damages "are only determined if and after a plaintiff has proven liability." *Hertzfeld v. Hayward Pool Prods., Inc.*, No. L-07-1168, 2007 WL 4563446, at *10, ¶ 71 (Ohio App. 6th Dist. Dec. 31, 2007). Therefore, the Court dismisses Count V without prejudice.

V. Conclusion

Accordingly, Defendants Ethicon, Inc. and Johnson & Johnson's Amended Motion for Summary Judgment (ECF No. 104) is denied in part and granted in part. The Court dismisses Plaintiff's claim for punitive damages (Count V) without prejudice to Olszeski's ability to obtain such damages should she prevail on one or more of her claims, and, in doing so, provide an evidentiary basis for a punitive damages charge and verdict.

Counsel are reminded that this case is set for a jury trial on April 11, 2022 at 9:00 a.m. *See* Order (ECF No. 122); Civil Trial Order (ECF No. 53).

IT IS SO ORDERED.

March 16, 2022
Date

/s/ Benita Y. Pearson
Benita Y. Pearson
United States District Judge